

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Prina FISHMAN

Application No.: 09/700,751

Filed: January 4, 2001

For: PHARMACEUTICAL COMPOSITIONS COMPRISING AN ADENOSINE RECEPTOR ...

Conf. No. 4072

Art Unit: 1623

Examiner: P. Lewis

Washington, D.C.

Atty.'s Docket: FISHMAN-4

Date: November 22, 2004

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VIA TELEFACSIMILE

THE COMMISSIONER OF PATENTS
2011 South Clark Place, Mail Stop Non-Fee Amendment
Crystal Plaza Two, Lobby, Room 1803
Arlington, VA 22202

Sir:

Transmitted herewith is a ☒ Second Supplemental Response ☒ ~~Relist Declaration, Ceren Study No. 6842 Report, Fishman Declaration, two Uzerman declarations~~
in the above-identified application.

☒ Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

☐ No additional fee is required.

☐ The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA EQUALS
TOTAL	* 44	MINUS	** 56	0
INDEP.	* 8	MINUS	*** 7	0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

SMALL ENTITY	
RATE	ADDITIONAL FEE
x 0	\$
x 43	\$
+ 145	\$
ADDITIONAL FEE TOTAL	

OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE
x 18	\$
x 56	\$
+ 280	\$
TOTAL	

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- ** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.
- *** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

☒ Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

☒ It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity
Response Filed Within

- ☐ First - \$ 55.00
☐ Second - \$ 210.00
☐ Third - \$ 475.00
☐ Fourth - \$ 740.00

Month After Time Period Set

Other Than Small Entity
Response Filed Within

- ☐ First - \$ 110.00
☐ Second - \$ 420.00
☐ Third - \$ 850.00
☐ Fourth - \$ 1480.00

Month After Time Period Set

☐ Less fees (\$) already paid for month(s) extension of time on

☐ Please charge my Deposit Account No. 02-4035 in the amount of \$

☐ Credit Card Payment Form, PTO-2036, is attached, authorizing payment in the amount of

☐ A check in the amount of \$ is attached (check no.).

☒ The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

BROWDY AND NEIMARK, P.L.L.C.

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Atty. Docket: FISHMAN=4

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Pnina FISHMAN)	Art Unit: 1623
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Appln. No.: 09/700,751)	Examiner: P. Lewis
)	
Filed: January 4, 2001)	Washington, D.C.
)	
For: PHARMACEUTICAL COMPOSITIONS)		November 22, 2004
COMPRISING AN ADENOSINE)		
RECEPTOR AGONIST OR ...)		VIA TELEFACSIMILE

SECOND SUPPLEMENTAL RESPONSE

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Non-Fee
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

The present communication is intended to supplement applicant's amendment of January 12, 2004, and applicant's supplemental amendment of July 21, 2004. It is respectfully requested that this supplemental response be admitted pursuant to 37 C.F.R. §1.111(a)(2), which became effective on October 21, 2004. The present supplemental response submits four declarations, one of which is directed to tests that have recently been conducted to prove that a compound of one of the references does not fall within the scope of the claims, and the others explain the results of those tests. The tests were

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commenced prior to the promulgation of the rule package that was published in the Federal Register on September 21, 2004. Thus, at the time that these tests were commenced, applicants were not aware that a ban on supplemental responses being submitted as a matter of right would come into effect on October 21, 2004. Accordingly, it is urged that the examiner exercise his discretionary authority to enter this supplemental reply, assuming that this supplemental reply reaches the examiner in sufficient time to be entered into the application filed before the examiner considers the prior replies. In the explanatory notes accompanying the rule-making package of September 21, 2004, the following statement appears at 69 FR 56517 (2004):

Examiners may enter and consider other supplemental amendments that are not listed in Section 1.111(a)(2)(i).

From this, it is clear that the examiner has the discretion to enter this response. Accordingly, this response should be entered because of the special situation that the tests reported in the declaration were commenced prior to the promulgation of the new rules, and it would therefore be unfair to apply them to the present supplemental reply in the present case.

Furthermore, the present supplemental response should be entered in accordance with 37 C.F.R. §1.111(a)(2)(i)(C) or (F), as it is believed that all of the

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prior issues were sufficiently addressed in applicant's amendment of January 12, 2004, and applicant's supplemental amendment of July 21, 2004, to require withdrawal of all of the rejections, with the possible exception of the anticipation rejection over Mittelman. Previously, applicant argued that this rejection should be withdrawn in view of the statement of the inventor in a declaration that the IPA of Mittelman is not an A3-selective adenosine receptor agonist. The present supplemental response now supports that opinion with factual data that will either place the case into condition for allowance, or at least eliminate the novelty rejection over Mittelman, thus simplifying issues for appeal.

In the last official action of July 10, 2003, claims 10, 11, 15, 16, 20, 41-43, 46 and 47 were rejected under 35 U.S.C. §102(b) as being anticipated by Mittelman. The examiner stated that Mittelman teaches that N⁶-(benzyladenosine) is a potent cytokinin and active in the mouse leukemia system. The examiner considers that G-CSF production is inherent to the disclosed compound. In applicant's amendment of January 12, 2004, applicant explained that the IPA and N⁶-(benzyladenosine) of Mittelman were not A3-specific adenosine receptor agonists in light of a statement to this effect in paragraph 15 of the Fishman declaration attached to the amendment of January 12, 2004.

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In order to provide more specific experimental support for this statement of Dr. Fishman, the present assignee sponsored a study at the French company Cerep to perform a binding analysis of the IPA from the Mittelman reference. Attached hereto is a declaration by Gervais Neliat, who is a principal scientist, pharmacology, in Cerep, and who can attest by firsthand information to the accuracy and completeness of the experimentation described in the report, which is attached to that declaration. The report explains the experimentation that establishes the binding affinities of IPA to the various adenosine receptors. Please note that IPA is referred to in the study by an alternative trivial name - 6(γ,γ -dimethylallylamino) purine riboside. Also attached is a declaration by Phina Fishman correcting the date of her previous declaration and explaining the rationale of the study, and including some comments as to the conclusions therefrom. Finally, further attached hereto are two declarations by Dr. Ad P. IJzerman. His declaration signed June 29, 2004, presents his opinion about the unobviousness of the present invention over Mittelman. His declaration signed November 15, 2004, analyzes the data from the study and also concludes that IPA is indeed not an A3-adenosine receptor agonist.

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While Mittelman refers to N⁶-(benzyladenosine) as well as IPA, it can be seen from the Mittelman reference that the formulae of the two compounds are very similar, and it can be seen from the discussion section at pages 232-233 that both have extremely similar pharmaceutical properties, that their toxicities are quite similar and both can be absorbed from the gastrointestinal tract, and both are capable of inducing remission in the human neoplastic disease. Because of their similarities of formula and similarities of action as taught by Mittelman, one would expect that their A3-receptor agonist selectivities are also similar. Thus, this data rebuts the presumption that these compounds are inherently A3-selective. As IPA, which has substantially the same activity as N⁶-(benzyladenosine), has proven not to be an A3-specific adenosine receptor agonist, there is no longer reason to believe that N⁶-(benzyladenosine) is A3-selective. In other words, the data as to one of the two compounds taught by Mittelman as behaving substantially the same in his tests should be sufficient to establish that there can be no presumption that either of them are A3-specific. Accordingly, consideration of the present declaration evidence in conjunction with applicant's amendment of January 12 and July 21, 2004, and reconsideration and withdrawal of the rejection over Mittelman are respectfully urged.

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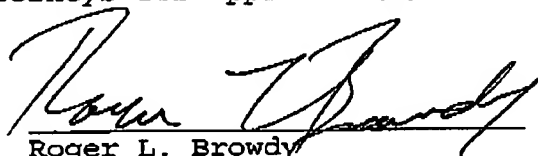
Reply to Office action of July 10, 2003

As applicant's amendments of January 12 and July 21, 2004, as supplemented by the present second supplemental response, establish that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112, reconsideration and allowance are earnestly solicited.

Respectfully submitted,

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Attorneys for Applicant(s)

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this Second Supplemental Response is being facsimile transmitted to the Patent and Trademark Office, on the date shown below.

Jonathan Brammer

Name



Signature

November 22, 2004

Date